REMARKS

Introductory Remarks

Claims 1-74 are pending in the application. Claims 1-30 and 60-74 are withdrawn from further consideration without prejudice.

Claims 57 and 58 are canceled herewith without prejudice, as the elements are present in claims 31 and 43, respectively.

Therefore, claims 31-56, and 59 remain under consideration.

Rejection under 35 U.S.C. 112, First Paragraph

The Office Action has rejected claims 31-59 under 35 U.S.C. 112, first paragraph, as allegedly introducing New Matter. The Office Action alleges that [T]he specification as filed does not provide such written description of the phrase "about 25 mg/ml to **about 200 mg/ml**" other than range of "about 25 mg/ml to **about 250 mg/ml**" on p. 22 lines 1-2 of the specification. (Emphases in the Office Action) Applicants respectfully traverse the rejection and provide following remarks.

Applicants reproduce the relevant sections from the Specification for the discussion (Paragraphs [0100-0102], Specification at pages 21-22).

> **[0100]** The amount of the diluent added to the powder is an amount such that the resulting concentration is suited to the intended application. Those of ordinary skill in the art know or can experimentally determine an appropriate antibody concentration for any given application. Typically, however, the concentration of the antibody in the reconstituted composition is about 1000 mg/mL or less. Thus, for example, completely spray drying a feed liquid comprising 1000 mg of an antibody and completely recovering the entire spray-dried powder will require 1 mL of diluent to form a reconstituted composition having an antibody concentration of 1000 mg/mL, 2 mL of diluent to form a reconstituted composition having an antibody concentration of 500 mg/mL, and so forth.

[0101] For subcutaneous administration, a preferred concentration range of the antibody in the reconstituted composition is from about 25 mg/mL to about 750 mg/mL, more preferably from about 25 mg/mL to about 500 mg/mL, still more preferably from about 50 mg/mL to about 450 mg/mL, yet still more preferably from about 70 mg/mL to about 400 mg/mL, and still more preferably from about 100 mg/mL to about 300 mg/mL. Another preferred range of the antibody is from about 25 mg/mL to about 250 mg/mL.

[0102] With respect to intravenous administration, exemplary antibody concentrations include from about 2.5 mg/mL to about 100 mg/mL, from about 5 mg/mL to about 75 mg/mL, and from about 10 mg/mL to about 50 mg/mL.

The Specification teaches that the spray dried antibody powders may be reconstituted anywhere from about 2.5 mg/mL to about 1000 mg/mL. Further, the specification teaches that depending on the route of administration (among other things), one skilled in the art may choose varying reconstituted concentrations. Furthermore, the Specification specifically mentions the following concentrations: 2.5 mg/mL, 5 mg/mL, 7.5 mg/mL, 10 mg/mL, 25 mg/mL, 25 mg/mL, 50 mg/mL, 70 mg/mL , 75 mg/mL, 100 mg/mL, 250 mg/mL, 300 mg/mL, 400 mg/mL, 450 mg/mL, 500 mg/mL, 750 mg/mL, and 1000 mg/mL. Further, a careful reading of Example 1 at page 37, paragraph [0160] reveals that spray dried formulations reconstituted at 50, 100, and 200 mg/mL maintained protein integrity and were stable.

Thus, Applicants here are describing series of ranges for various preferred embodiments, which set boundaries for what is within the range for a specific preferred embodiment. A range encompasses all variables that are within that range. A range is not its edges only. Applicants submit that all of the concentrations between about 2.5 mg/mL to about 1000 mg/mL are encompassed and enabled, and that Applicants could choose any concentration between these limitations to write their claims.

To the extent that the exact phrase "about 25 mg/mL to about 200 mg/ mL" together in claim 31 represents the introduction of "new matter," Applicants respectfully submit that such a position is contrary to well-established case law in that a disclosure including multiple ranges

provides adequate support for reciting portions of those ranges. *See In re Wertheim*, 191 USPQ 90 (CCPA 1976) (range of 25 to 60% with examples at 36% and 50% found to be adequate description for a range of 35 to 60%); In re Voss, 194 USPQ 267 (CCPA 1977) (range of 20 to 100% provided description for range of 50 to 100%); In re Blaser, 194 USPQ 122 (CCPA 1977) (range of 60 to 200°C provided adequate description for 80 to 200°C); In re Waymouth, 179 USPQ 627 (CCPA 1973) (range of 450 to 700°C was claiming same range as claim specifying a minimum temperature of 580°C); McLaughlin v. Roberts, 197 USPQ 831 (Bd. Pat. App. & Int. 1978) (range of 10 to 79% with preferred ranges of 40 to 79% and 40 to 60% provided adequate support to claim range of 10 to 25%). Therefore, Applicants submit that it is improper for the Office to conclude that "about 200 mg/mL" is not supported by the Specification.

Applicants submit that in view of the foregoing the amendments to claim 31 are appropriate, and respectfully submit that rejection based on 35 USC 112, first paragraph should be withdrawn.

Rejection under 35 U.S.C. 102(b)

The Office Action has rejected claims 31-59 under 35 U.S.C. 102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958).

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

The Office Action states that the "patentability of the product does not depend on its method of production." Citing Andya et al. at claims 1-8 and 47 and column 17, lines 1-40, and Table 5-6, in particular, the Examiner alleges that the claimed antibody formulation and the referenced antibody formulation both comprise an antibody, diluent, buffer and sucrose as an excipient. The Examiner concludes that "being visually clear upon reconstitution within about 10min" is inherent property of the antibody composition comprising antibody, histidine and polysorbate."

In response, Applicants point out that the claims do not simply recite a reconstituted composition being "visually clear upon reconstitution." Instead, the claims recite (among other things) that the reconstituted composition "is a visually clear reconstituted composition within about

10 minutes of being formed." Emphasis added. In view of the different reconstitution times associated with the lyophilized formulations shown in the specification at paragraph **[0162]** (which are also of the type disclosed in Andya et al.) and the spray dried formulations encompassed by the claims, it simply cannot be said that a visually clear reconstituted composition within about 10 minutes of being formed is "an inherent property of antibody formulations" generally.

Again, Applicants emphasize that their claims require a reconstituted composition having the feature of visual clarity within about 10 minutes of being formed. Applicants have specifically demonstrated that reconstituted lyophilized compositions -- such as the type disclosed in Andya et al. – will not inherently become a visually clear reconstituted composition within about 10 minutes of being formed. Further, a close reading of Andya et al. only reveals that the "time required for reconstitution will depend, e.g., on the type of diluent, amount of excipient(s) and protein." See Andya et al. at Column 17, lines 23-25. In addition, Andya et al. fails to disclose the feature of a spray-dried powder, a feature recited in the only pending independent claim. Consequently, as the cited art fails to teach each and every feature recited in the claims, Applicants respectfully request that the rejection of claims 31-59 under 35 U.S.C. 102(b) should be removed. Reconsideration and removal of the rejection are respectfully requested.

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CONCLUSION

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 631-3286.

Respectfully submitted,
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